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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,152

02/20/2004

Rafail Zubok

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07/21/2009

SPINE MP

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WESTFIELD, NJ 07090

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,152	Applicant(s) ZUBOK ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9,11,12,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,9,11,12,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/09 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3,4,9,11 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bagga et al. (2003/125739) in view of Neumann (EP 1219266). Figs. 26,27 show a distraction instrument **310** in the form of a plying device with at least two hinges that includes a pair of extension forks **320,330** with two tines each. It can be seen that the axis of the tines is offset from the axis of the handles. Fig. 23 shows that the extensions extend from an elongate base and includes a ridge perpendicular to the outward facing surface of the tines. This ridge forms a vertebral body stop. Regarding claim 9, the device is capable of distracting, paragraph 141. Fig. 25 shows that the extensions have a notch since they do not lie in the same

Art Unit: 3738

plane as the base of the extension and the forks extend up and outward from the base.

Figs. 4,12,15 show the perimeter surfaces of the implant are rounded and thus, the instrumentation having the fork extensions that engage the implant would be curved or have a curved profile.

However, in the alternative Bagga does not explicitly show the interior surface having a curved profile. Neumann teaches (Figs. 11,12) that the interior surface of an instrument including tines for holding a spinal implant has curved profiles as is illustrated to engage the curved profile of the implant and is also notched.

Please note the examiner is interpreting the claimed element notch in this way: a narrow passageway. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Therefore, it is noted that both Bagga and Neumann can be considered to have "notched areas". It would have been obvious to one of ordinary skill in the art to form the implant engaging interior surfaces of the fork-shaped extensions such that they are curved with a notched areas in the profile as taught by Neumann with the distractor tool of Bagga et al. such that it a secure engagement with no opportunity for translational movement.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagga et al. (2003/125739) in view of Neumann (EP 1219266) as applied to claim 1 above, and further in view of Rinner et al. (6551316). Bagga et al. as modified with Neumann is explained supra. However, Bagga in view of Neumann does not disclose the fork shape extensions are releasable. Rinner et al. teach (Fig. 1) a distraction instrument in the form of a plying device with detachable fork shaped extensions **13,14**. Rinner also teaches that the versatility of the releasable components gives the surgeon advantageous delivery precision, col. 1, lines 39-44. It would have been obvious to one of ordinary skill in the art to use releasable end extensions as taught by Rinner et al. with the plying distractor of Bagga et al. as modified with Neumann such that it provides the surgeon with the necessary capabilities in delivering an implant to a delicate location such as between the vertebrae.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagga et al. (2003/125739) in view of Aebi et al. (6261296) and Neumann (EP 1219266). Bagga et al. is explained supra. However, Bagga does not disclose the system used with a spinal implant having two baseplates or alternatively that the interior sides of the fork extensions have a notched curved profile. Aebi et al. teach (Fig. 3) a distraction instrument in the form of a plying device with fork shaped extensions. Aebi also shows that the implant to be inserted with the instrument is a spinal device with upper and lower baseplates, Fig. 5. It would have been obvious to one of ordinary skill in the art to use distraction device with fork shaped extensions also with a spinal implant with baseplates as taught by Aebi et al. using the plying distractor of Bagga et al. such that it

Art Unit: 3738

provides the surgeon with the necessary capabilities and provides the proper implant to suit the patient's needs. Neumann is explained supra. Alternatively, it would have been obvious to one of ordinary skill in the art to form the implant engaging interior surfaces of the fork-shaped extensions such that they are curved with a notched areas in the profile as taught by Neumann with the distractor tool of Bagga et al. modified with Aebi such that it a secure engagement with no opportunity for translational movement.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagga et al. (2003/125739) in view of Aebi et al. '296 and Neumann as applied to claim 16 above, and further in view of Buttner-Janz et al. (5401269). Bagga in view of Aebi et al. and Neumann is explained above. It is noted that both Bagga and Aebi does disclose teeth on the implant, see Figures. However, Bagga as modified by Aebi and Neumann fail to disclose teeth spaced apart from a centrally disposed dome. Buttner-Janz teaches (Figs. 3,4) a centrally disposed dome between the plates and teeth spaced apart towards the perimeter of the plates and on the exterior surface such that they are apart from the dome. It would have been obvious to one of ordinary skill in the art to incorporate the teeth as placed on the exterior surface of the plates taught by Buttner-Janz in substitution of the teeth of Bagga's implant as modified by the teachings of the Aebi et al. implant and that of Neumann regarding the tool surface engagement and incorporate an articulating dome centrally within the plates as taught by Buttner-Janz for the device of Bagga in view of Aebi such that it allows the device to permit articulation in a patient not requiring fusion.

Response to Arguments

Applicant's arguments with respect to claims 1,16 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that Bagga et al. do not explicitly disclose a curved profile for the interior surface of the distractor tool. As noted by Applicants and the Examiner, the rounded profile of the implant surface would likely engage structure of the tool. The Examiner is not persuaded and it may be implied, but in the alternative as presented in the above rejection, the prior art and other instruments known to those of skill in the art teach to match contours of engaging structures, the implant and its tool. Therefore, as taught by the prior art an interior surface is curved and would match the curved profile of the implant surface. Regarding the comments made by the Applicants with respect to interpretation of the limitation of a "notch" and the Examiner interpreted it overly broad. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. Since no special definition was given with respect to the term, it can be considered as mentioned above, a narrow passage is presented by the tool of Bagga in a region or area that is interior to the profile of the fork shaped extensions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738